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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,666	02/11/2005	Katsuaki Miyaji	265792US0PCT	1538
22850 7590 08/05/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
			EXAMINER SACKEY, EBENEZER O	
			ART UNIT 1624	PAPER NUMBER
			NOTIFICATION DATE 08/05/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## Office Action Summary

Application No.

10/524,666

Applicant(s)

MIYAJI ET AL.

Examiner

EBENEZER SACKEY

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-15, 18 and 19 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 and 17 is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/11/05, 5/31/05, 8/29/08</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of the Claims**

Claims 1-19 are pending.

### ***Specification***

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Information Disclosure Statement***

Receipt of the Information Disclosure Statement filed on 02/11/05; 05/31/05 and 08/29/07 respectively is acknowledged and has been entered into the file. Signed copies of the 1449 are attached herewith.

***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:  
It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either an application data sheet or supplemental oath or declaration.

***Response to Restriction***

Applicant's election without traverse of Group I, claims 1-8 and 16-17 in the reply filed on 02/11/08 is acknowledged.

Claims 9-15 and 18-19 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to non-elected subject matter.

***Claim Objections***

Applicant is being advised that should claim 1 be found allowable, claim 8 will be objected to under 37 CFR 1.75 as being substantial duplicate thereof. Note that there is no difference in the preamble in each of the claims. The specification has support for one compound. Claim 1 has all the listed properties and therefore claim 8 is considered as a substantial duplicate of claim 1. If applicants choose to argue or admit on the record that the claims are different, a restriction of the claims may be appropriate then. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other claim under 37 CFR 1.75 as being a substantial duplicate of the allowed claim. See MPEP.... 706.03(k). Note in the

absence of a material difference in scope, the two claims cover the same subject matter. If applicants cannot show that infringing one set of claims does not infringe the other set as well, then one set needs to be cancelled. Note In re Vogel, 164 U.S.P.Q. 619.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds on pages 35-39, does not reasonably provide enablement for solvate or prodrugs of those compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claim recites specific compounds of structural formula (I) and solvates and prodrugs of said compounds. However, the specification fails to teach the preparation of solvates or prodrugs. Therefore, the specification is not adequately enabled for solvates.

Identifying a solvate requires knowledge of properties of the solvents and solutes of the instant compounds and nothing short of extensive testing (none identified) would be needed to determine if additional derivatives exist thus, such a scope as literally claimed herein is non-enabled.

The examples presented all fail to produce a solvate or a prodrug. These

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cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ 2d 1190 "the specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However, .... there is no evidence that such compounds exist..... the examples of the '881' patent do not produce the postulated compounds.....there is ....no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compositions actually exist; if they did, they would have been formed. Hence, applicants must now show that solvates can be made, or limit the claims accordingly.

It is not the norm that one can predict with any accuracy a particular solvate form of an active compound will be more soluble, more easily handled in formulations or more bioavailable without actual testing in vivo. The specification provides no guidance as to what type(s) are suitable for instant compounds.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (*In re Wands*, 8 USPQ2d 1400, 1404 (CAFC, 1988)):

- 1) Nature of invention.
- 2) State of prior art.
- 3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.

8) Level of ordinary skill in the art.

See below:

1) Nature of the invention.

The nature of the invention is the preparation of compounds and compositions under the genus of structural formula (I). As stated, however, solvates and prodrugs are also intended.

2) State of the prior art .

The state of the prior art is that solvates are known in the pharmaceutical industry.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue. For example, identifying a solvate requires knowledge of the properties of the solvents and solutes and their reactions and/or transformation, nothing short of extensive testing (none identified) would be needed to determine if additional derivatives exist and thus, such a scope as literally claimed herein is non-enabled.

4) Level of predictability in the art.

The art pertaining to the preparation and use of solvates are high as solvates are compound specific.

5) Amount of direction and guidance provided by the inventor.

There is no guidance provided as all the examples in the specification are drawn to the preparation of compounds and not solvates. Additionally, the specification provides no guidance as to what type(s) solvates are suitable for the instant

compounds.

6) Existence of working examples.

No examples of solvates have been provided in the specification.

7) Breadth of claims.

The breadth of the recited compounds and the solvates render the claims overly broad.

8) Level of ordinary skill in the art.

The level of ordinary skill in the art is high due to the unpredictability in the chemical art.

Hence, the specification fails to provide sufficient support for solvates as claimed herein. As a result, necessitating one of ordinary skill in the art to perform an exhaustive search to determine which of the claimed solvates can be employed to practice the claimed invention.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

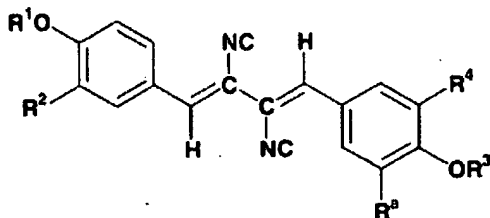
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102 (b) as being anticipated by  
Tsuruoka ET al., (U.S. Patent number 5,312,833).



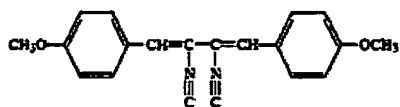
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Applicants claim compounds of structural formula (I), where the substituents are as



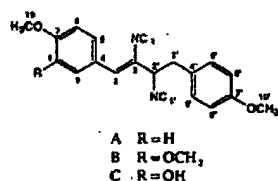
defined

Tsuruoka et al., discloses a compound (species) under the genus of formula (I) when each of R<sup>1</sup> and R<sup>3</sup> is a methyl and each of R<sup>2</sup>, R<sup>4</sup> and R<sup>5</sup> is hydrogen. See structural

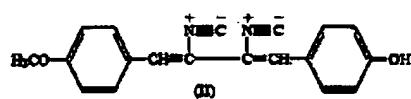


formula (I)

Morino et al., also disclose species under the genus of formula (I):



Kurihara et al., disclose compounds under the genus of formula (I). See formula (I)



, this reference is replete with anticipatory compounds such

as **Compound No. 1: 1-(4'-ethoxycarbonyloxyphenyl)-4-(4'-methoxyphenyl)-2,3-dicyano-1,3-butadiene,**

It is noted that the preamble recites "thrombopoietin receptor activator" compound.

However, the intended use of the compound is not given any patentable weight.

Therefore, the claims are interpreted as compound claims.

Claims 16 and 17 are allowed over the prior art of record.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. Sackey whose telephone number is (571) 272-0704. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

EOS

**/James O. Wilson/**

**Supervisory Patent Examiner, Art Unit 1624**